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| 09/751,769 | 12/29/2000 | Judith K. Gwathmey | JGT-002 | 5078 |
| 959 | 7590 | 03/21/2002 | EXAMINER | |
| LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109 | | | SAUNDERS, DAVID A | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1644 | | |
| DATE MAILED: 03/21/2002 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|--------------------------|--------------------------|
| Application N 751,769 | Applicant(s) GWATHMEE |
| Examiner SAUNDERS | Group Art Unit 1644 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on _____.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- Claim(s) 1-29 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) _____ is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) 1-29 are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - All
 - Some*
 - None of the CERTIFIED copies of the priority documents have been
 - received.
 - received in Application No. (Series Code/Serial Number) _____.
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892
- Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Other _____

Office Action Summary

DETAILED ACTION

Restriction Requirement

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-12, drawn to an iron chelator delivery system comprising an iron chelator and a lipid carrier; classified in Class 514, subclass 502 and Class 424, subclass 450.
 - II. Claims 13-15, drawn to a method of preparing an iron chelator deliver system, classified in Class 436, subclass 829.
 - III. Claims 16 and 17, drawn to a method of preparing an iron chelator deliver system, classified in Class 436, subclass 829.
 - IV. Claims 18-29, drawn to a method of treating iron-overload by administering an iron chelator delivery system, classified in Class 514, subclass 502 and Class 424, subclass 450.
3. Groups II/III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case, the iron chelator delivery system can be made by either of the methods of Groups II or III which involve a materially different process comprising distinct method steps.

In addition, these processes as claimed can be used to prepare other materially different products which comprise any of the particular combinations of iron chelators and lipid carriers.
4. Groups I and IV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the iron chelator delivery system can be used to deliver chelators for metals other than iron, and also can be used in diagnostic applications in addition to the method of treating recited.

5. Groups II/III and IV are different methods. Each method of preparing differs with respect to ingredients and method steps. In addition, a method of preparing an iron chelator delivery system and a method of treating differ with respect to ingredients, method steps and endpoints. Therefore, each method is patentably distinct.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the distinct method steps recited. Moreover, a prior art search also requires a literature search, which would not be completely co-extensive. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

7. Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the individual combinations of a specific iron chelator (such as one of those recited in claim 2) and a specific lipid carrier (such as those recited in claims 4 or 7-10). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Claim 18 is generic to a plurality of disclosed patentably distinct species comprising the individual combinations of a specific iron chelator (such as one of those recited in claim 19) and a specific lipid carrier (such as those recited in claims 21, 23-25 or 27). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1644

9. This application contains claims directed to the following patentably distinct species of the claimed inventions of Group II and III: wherein the iron chelator is one of the iron chelators recited in instant claims 15 (Group II) and 17 (Group III).

These species of iron chelators are patentably distinct because each differs from the other with respect to their structures and functional properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 13 (Group II) and 16 (Group III) are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders whose telephone number is (703) 308-3976. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

David A. Saunders, Ph.D.
Patent Examiner
Technology Center 1600
March 19, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1644